

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of low Frequency TENS on postural stability in patients with mechanical chronic low back pain

Protocol summary

Study aim

The primary aim of this study is to investigate the possible effect of TENS on postural control in patients with chronic low back pain.

Design

The participants are assigned randomly to the intervention or the control groups with a block randomization method using excel software. Twenty eight participants (14 patients in each group) are enrolled in this randomized controlled trial study.

Settings and conduct

This study is done at the research center of the Shiraz University of Medical Sciences and they are referred to a physiotherapy clinic in the hospitals of the University. The participants then are assigned randomly to the intervention or the control groups.

Participants/Inclusion and exclusion criteria

In this study, twenty eight low back pain patients participate are included between 25 to 45 years old with at least 6 months low back pain in the low back area and pain intensity of more than 3 on a Visual Analog Scale (VAS). The participants with a history of sciatica or other radicular involvement, and spinal surgery are also excluded. All participants are recruited from referrals of local physiotherapy clinics in Shiraz. Then, patients by using block randomization allocate in intervention and control group.

Intervention groups

We perform low frequency TENS for both groups. Intervention group are positioned prone on a treatment bench; then, Low frequency electrical stimulation with the duration of 250 μ s and 2 HZ frequency through surface electrodes placed at between spinus process L1 and L5 bilaterally for 20 minutes at tolerance level. In control group, protocol are done like to intervention group but they receive placebo electrical stimulation. postural control assess before, immediately and 24 hours after of the TENS application. We expect that TENS improve postural control in low back pain patients.

Main outcome variables

Pain, Static and dynamic balance

General information

Reason for update

Since our study is prospective and the starting date of the sample entry was mistakenly entered on April 21, 2013, instead of February 8, 2014, we made the desired corrections.

Acronym

Balance and chronic low back pain

IRCT registration information

IRCT registration number: **IRCT201305292391N11**

Registration date: **2014-01-31, 1392/11/11**

Registration timing: **prospective**

Last update: **2020-05-08, 1399/02/19**

Update count: **1**

Registration date

2014-01-31, 1392/11/11

Registrant information

Name

Zahra Rojhani Shirazi

Name of organization / entity

Shiraz University of Medical Sciences, School of Rehabilitation Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1627 1552

Email address

rojhaniz@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences - Shiraz Faculty of Rehabilitation

Expected recruitment start date

2014-02-08, 1392/11/19

Expected recruitment end date

2014-06-11, 1393/03/21

Actual recruitment start date

2014-03-05, 1392/12/14

Actual recruitment end date

2014-07-15, 1393/04/24

Trial completion date

2014-07-15, 1393/04/24

Scientific title

Evaluation of the effect of low Frequency TENS on postural stability in patients with mechanical chronic low back pain

Public title

Effect of electrical stimulation on mechanical low back pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The participants are included between 25 and 45 years old with at least 6 months low back pain in the area between the gluteal fold and the 12th rib, pain intensity of more than 3 on a Visual Analog Scale (VAS), and Oswestry questionnaire score of 0 to 40% (mild to moderate disability).

Exclusion criteria:**Age**

From **25 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **28**

Actual sample size reached: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee, Shiraz University of Medical Sciences

Street address

Ethics Committee, Shiraz University of Medical Sciences, Zand blv.

City

Shiraz

Province

Fars

Postal code

0

Approval date

2013-09-23, 1392/07/01

Ethics committee reference number

CT- 92- 6511

Health conditions studied**1****Description of health condition studied**

Mechanical chronic low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes**1****Description**

Balance

Timepoint

Immediately , after 30 min

Method of measurement

Force plate

Secondary outcomes

empty

Intervention groups**1****Description**

Low frequency TENS(low frequency TENSwith the pulse duration of 250 μ s and 2 HZ frequency through surface electrodes placed at between spinus process L1 and L5 bilaterally for 20 minutes at tolerance level). Intervention group is positioned prone on a treatment bench; then, electrical stimulation applies via an surface electrical stimulations places at between spinus process L1 and L5 in each sides for 20 minutes at tolerance level. Control group receives placebo electrical stimulation.Treatment is carried out for 8 sessions in 2 weeks.

Category

N/A

2

Description

Low frequency TENS with the pulse duration of 250 μ s and 2 HZ frequency through surface electrodes placed at between spinus process L1 and L5 bilaterally for 20 minutes at tolerance level. Control group is positioned prone on a treatment bench; then, electrical stimulation applies via an surface electrical stimulations places at between spinus process L1 and L5 in each sides for 20 minutes. This group receives placebo electrical stimulation. Treatment is carried out for 8 sessions in 2 weeks.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

physiotherapy clinic in the hospitals of the Shiraz University of Medical Sciences

Full name of responsible person

Zahra Rojhani Shirazi

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Shiraz Faculty of Rehabilitation Sciences, Chamran blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Gholamreza Hatam

Street address

Shiraz University of Medical Sciences

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Shiraz

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Phone

+98 71 3627 2495

Email

rojhaniz@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Rojhani Shirazi

Position

PHD

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

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Shiraz University of Medical Sciences

Full name of responsible person

Zahra Rojhani Shirazi

Position

PHD

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Some of the data, such as information about the
consequences, can be shared.

**When the data will become available and for how
long**

Starting the access period: 6 months after publish the
results.

To whom data/document is available

Researchers working in academic and academic
institutions.

Under which criteria data/document could be used

Only statistical analyzes can be used to find treatment
for improvement of patients.

From where data/document is obtainable

Applicants can be guided by email authors.

**What processes are involved for a request to access
data/document**

First, they will email the authors of the study and we will
be answered within a week.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Rojhani Shirazi

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Latest degree

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Other areas of specialty/work

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